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Short-Term Pregnancy Outcomes Following Monoclonal Antibody Treatment for COVID-19 Infection during the Omicron Surge

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Abstract

Background: Monoclonal antibody (mAb) therapy has been recommended in non-hospitalized COVID-19 positive pregnant individuals with mild to moderate symptoms despite data on safety and efficacy.

Objective: To assess short-term outcomes of mAb treatment in COVID-19 positive pregnant patients during the Omicron surge.

Methods: This is a descriptive study of pregnant patients receiving mAb therapy from December 1, 2021, and March 18, 2022 during the Omicron surge. Patients received either (1) sotrovimab, or (2) bamlanivimab/etesivimab, or (3) casirivimab/imdevimab. We reviewed the medical records of pregnant patients who received mAb, gathering baseline demographics and assessing adverse events from mAb infusion.

Results: Twenty-one pregnant patients received mAbs during the Omicron surge. The short-term maternal outcomes for most of our cohort were favorable. One patient developed an anaphylactic reaction following infusion of bamlanivimab/etesevimab. One patient required admission to the intermediate care unit for severe COVID-19 fifteen days following infusion, and a second patient developed cardiorespiratory symptoms concerning for post-acute sequelae SARS-CoV-2 infection. Adverse pregnancy outcomes were present in 43.7% of our delivered cohort (n=16).

Conclusion: Short-term outcomes in pregnant patients who received monoclonal antibodies for COVID-19 during the Omicron surge are mostly favorable, with symptom resolution and rare adverse events.

Keywords: Omicron Surge; Cardiorespiratory Symptoms; COVID-19; Monoclonal Antibody

Abbreviations: MAB: Monoclonal Antibody; FGR: Fetal Growth Restriction; GHTN: Gestational Hypertension.

Introduction

Pregnant patients who contract severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) are at increased risk for developing pneumonia, acute respiratory distress syndrome, ICU admission, invasive ventilation and death compared with nonpregnant patients [1-3]. To prevent progression to severe disease, the use of monoclonal antibodies has been recommended in non-hospitalized COVID-19 positive pregnant individuals with mild to moderate symptoms. However, these monoclonal antibodies have not been well

studied in pregnancy, and there is insufficient evidence to determine overall safety and efficacy. Despite these concerns, monoclonal antibodies are being widely used in pregnancy, with recently reports suggesting that this therapy is well tolerated in pregnancy and prevents progression to severe disease [4-6]. Use of monoclonal antibodies has become further complicated by the recent emergence of the Omicron variant of SARS-CoV-2 as the dominant strain worldwide due to the potential for reduced effectiveness of monoclonal antibodies against this variant. One study showed a marked loss of inhibitory activity against the Omicron variant by several of the most highly neutralizing monoclonal antibodies currently in use [7].

Objective

The purpose of this case series was to assess short-term outcomes of mAb treatment in COVID-19 positive pregnant patients during the Omicron surge.

Study Design

This study was approved by the University of Connecticut Health Center IRB. Medical records of pregnant patients who received mAbs from December 1, 2021, through March 18, 2022 were reviewed. Patients were eligible to receive mAb treatment if they tested positive for SARS-CoV-2 based on nasopharyngeal polymerase chain reaction test, had symptoms within 7 days and did not meet criteria for admission. Patients received (1) sotrovimab, or (2) bamlanivimab/etesivimab, or (3) casirivimab/imdevimab in the emergency department or infusion center. Patients were monitored for 1-hour for adverse effects.

Results

Twenty-one pregnant patients received mAbs during the Omicron surge (Table 1). Of the 9 patients who were fully vaccinated, 4 had completed their booster. The average time from diagnosis to infusion was 3 days. The average gestational age at time of treatment was 26 weeks. Two patients received casirivimab/imdevimab and 5 patients received bamlanivimab/etesivimab, administered prior to the recommendation by the U.S. Food and Drug Administration that these mAb treatments should not be used when Omicron is suspected because of markedly reduced activity against this variant. The remainder of patients received sotrovimab.

The short-term maternal outcomes for most of our cohort were favorable. One patient developed an anaphylactic reaction following infusion of bamlanivimab/etesevimab. One patient required admission to the intermediate care unit for severe COVID-19 fifteen days following infusion, and a second patient developed cardiorespiratory symptoms concerning for post-acute sequelae SARS-CoV-2 infection.

Adverse pregnancy outcomes were present in 43.7% of our delivered cohort (n=16). One patient underwent cesarean delivery at 38w6d for worsening COVID-induced maternal hypoxia. One patient had spontaneous preterm birth of a healthy neonate at 35w2d and another patient was medically induced at 34w0d for superimposed preeclampsia with severe features. Four patients underwent a medical induction of labor at term for gestational hypertension (gHTN) (n=2), fetal growth restriction (FGR) in the setting of gHTN (n=1), and oligohydramnios (n=1). Of the four patients who remain pregnant with resolution of COVID-19, one is currently being followed for early-onset, severe FGR.

Conclusion

This case series describes short-term outcomes in 21 pregnant patients with SARS-CoV-2 who received mAb treatment during the Omicron surge, demonstrating that most patients who receive mAb treatment experience symptom resolution without the need for additional care. All but one patient tolerated mAb infusion without immediate adverse effects. Our study is limited by lack of a comparison group and hence, our conclusions run the risk of being non-representative. Further, we cannot draw definitive conclusions that our favorable patient outcomes were a direct result of mAB treatment and not due to other variables. Despite this limitation, our reassuring study findings are consistent with other studies evaluating patients receiving mAb treatment prior to the Omicron variant [8,9]. further research evaluating a larger; more diverse population of patients is warranted. In addition, more studies are needed to examine the efficacy and safety of mAbs against different variants during pregnancy, and long-term maternal and neonatal outcomes.

Gravida	Para	Gest. Age at COVID Diagnosis (weeks)	Symptoms at Diagnosis	Comorbidities	BMI (kg/m^2)	Treatment	COVID Day of Administration	Treatment Side Effects	Pregnancy Complications	Pregnancy Status	Gest. Age at Delivery (weeks)	Mode of Delivery	Birth-weight (g)	Neonatal Complications	Placental Pathology Findings
9	5	11+6	Fever, nausea, vomiting, headache, loss of taste/smell	None	29.4	casirivimab. imdevimab	2	None	Early onset severe fetal growth restriction, fetal mild cerebellar hypoplasia	Pregnant					
4	3	29+4	Headache, cough	Type I Diabetes, Asthma	25.06	casirivimab imdevimab	2	None	PASC*, Preterm labor at 35+1 weeks	Delivered	35+2	Vaginal	3480	NICU Admission	Placenta not sent
1	0	19+4	Cough, congestion, myalgias	Idiopathic Thrombocytopenic Purpura, Obesity, Obstructive sleep apnea	35	bamlanivimabetesevimab	2	None	Gestational hypertension, fetal growth restriction	Delivered	36+0	Vaginal	1920	NICU Admission	Mature placenta, focal mild acute chorionitis
3	2	17+1	Cough, rhinorrhea, sore throat	None	29.9	bamlanivimabetesevimab	0	None	None	Pregnant					
1	0	26+5	Congestion, extreme fatigue	None	27.6	sotrovimab	4	None	None	Delivered	39+6	Vaginal	3220	None	Placenta not sent
1	0	37+3	Fever, chills, headache, cough, myalgias	Obesity	33.59	sotrovimab	2	None	Hypoxia requiring hospital admission	Delivered	38+6	Cesarean	3150	None	Multifocal chronic lymphocytic villitis
1	0	10+0	Fever, cough, headache, sore throat, nausea, vomiting	None	22	sotrovimab	6	None	None	Pregnant					
3	1	23+3	Cough, chest pain, headache, myalgias	Obesity	44.1	bamlanivimabetesevimab	6	Anaphylaxis	Oligohydramnios	Delivered	38+4	Vaginal	3080	None	Placenta note sent
1	0	26+5	Cough, rhinorrhea, myalgias	Chronic Hypertension	44.5	bamlanivimabetesevimab	0	None	Superimposed preeclampsia with severe features	Delivered	34+0	Cesarean	2010	NICU Admission	Decidual vessels with thrombosis

4	3	23+6	Headache, myalgias, chest pain, nausea, vomiting	Chronic Hypertension	28.3	bamlanivimabetesevimab	2	None	Unexplained elevated msAFP (2.06 MoM)	Delivered	39+0	Vaginal birth after cesarean	3660	None	Placenta not sent
2	1	24+2	Headache, sore throat	None	29.48	sotrovimab	2	None	None	Delivered	38+0	Vaginal	3260	None	Placenta not sent
4	3	27+5	Cough, sore throat, nausea, myalgias	Obesity	35.6	sotrovimab	4	None	None	Delivered	39+4	Vaginal	3310	None	Placenta not sent
1	0	30+1	Nausea, vomiting	Obesity	37.1	sotrovimab	2	None	Fetal tachyarrhythmia (resolved during pregnancy)	Delivered	40+1	Vacuum assisted vaginal delivery	3620	None	Small placenta, chronic villitis
3	1	35+0	Shortness of breath	None	26.6	sotrovimab	5	None	None	Delivered	40+0	Vaginal	3630	None	Placenta not sent
2	1	26+1	Cough, congestion, rhinorrhea, chills	Obesity	37.1	sotrovimab	2	None	None	Delivered	39+1	Cesarean	3827	None	Placenta not sent
3	0	31+4	Cough, congestion, shortness of breath	None	28.72	sotrovimab	5	None	None	Delivered	39+2	Vaginal	3400	None	Placenta not sent
3	2	27+2	Congestion, myalgias	Asthma	20.9	sotrovimab	2	None	None	Delivered	38+4	Vaginal	3430	None	Placenta not sent
3	1	14+1	Congestion, headache, myalgias	Obesity	31.6	sotrovimab	4	None	None	Pregnant					
3	2	35+1	Congestion, nausea, myalgias	Obesity	37.4	sotrovimab	2	None	Gestational Hypertension	Delivered	39+5	Vaginal	3690	None	Placenta not sent
2	1	35+3	Cough	Obesity	34.6	sotrovimab	7	None	Gestational Hypertension	Delivered	37+5	Vaginal	2720	None	Placenta not sent
3	2	31+5	Fever, cough, congestion	Obesity	30.9	sotrovimab	2	None	Cholestasis of Pregnancy	Delivered at outside hospital	Un-known	Unknown	Un-known	Unknown	

*Post acute sequelae SARS-CoV-2 infection.

Table 1: Patient Demographics and Outcomes.

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